In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS
No. 21-0516V

CATHERINE KANE,

Petitioner,

v.

SECRETARY OF HEALTH AND HUMAN SERVICES,

Respondent.

Chief Special Master Corcoran

Filed: April 23, 2024

Diana Lynn Stadelnikas, Maglio Christopher & Toale, PA, Sarasota, FL, for Petitioner.

Mark Kim Hellie, U.S. Department of Justice, Washington, DC, for Respondent.

FINDINGS OF FACT AND DISMISSAL OF TABLE CLAIM[1]

On January 11, 2021, Catherine Kane filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §300aa-10, *et seq.*[2] (the "Vaccine Act"). Petitioner alleges that she suffered a right shoulder injury related to vaccine administration ("SIRVA"), a defined Table injury or, in the alternative a caused-in-fact injury, after receiving the influenza ("flu") vaccine on October 2, 2020. Petition at 1, ¶¶ 1, 14-15.

[1] Because this Fact Ruling contains a reasoned explanation for the action taken in this case, it must be made publicly accessible and will be posted on the United States Court of Federal Claims' website, and/or at https://www.govinfo.gov/app/collection/uscourts/national/cofc, in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2018) (Federal Management and Promotion of Electronic Government Services). **This means the Fact Ruling will be available to anyone with access to the internet.** In accordance with Vaccine Rule 18(b), Petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will redact such material from public access.

[2] National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all section references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2018).

For the reasons discussed below, a preponderance of the evidence supports the conclusion that the onset of Petitioner's right shoulder pain occurred *later* than 48 hours post-vaccination – meaning she cannot establish a Table SIRVA. Any causation-in-fact version of the claim will only succeed if Petitioner can provide preponderant evidence of a vaccine-caused injury consistent with the pain onset determined in this Ruling.

I. Relevant Procedural History

Approximately one month after the case's initiation, Ms. Kane filed her signed declaration,[3] the medical records required under the Vaccine Act, and her PAR Questionnaire. Exhibits 1-11, ECF Nos. 6-7; *see* Section 11(c). On May 7, 2021, the case was activated and assigned to the "Special Processing Unit" (OSM's adjudicatory system for resolution of cases deemed likely to settle). ECF No. 9.

On October 18, 2021, Respondent indicated he had not identified any outstanding medical records or factual issues which could be addressed while awaiting the HHS review. ECF No. 16. During this same time, Petitioner filed updated medical records on several occasions. Exhibit 12-15, ECF Nos. 14, 18-19. Petitioner began finalizing a demand in early 2022. ECF No. 21.

On June 2, 2022, Respondent indicated that he "[wa]s not interested in considering a demand at this time." ECF No. 25. Approximately 45 days later – on July 18, 2022, he filed his Rule 4(c) Report opposing compensation. ECF 26. Specifically, Respondent maintained that Petitioner has not met the Vaccine Act's severity requirement. *Id.* at 5-6 (citing Section 11(c)(1)(D)).

On March 7, 2023, I issued a Fact Ruling finding there was preponderant evidence to establish Petitioner suffered the residual effects of her alleged SIRVA for more than six months - the Vaccine Act's "severity requirement." ECF No. 30.[4] Noting that the issue had been a close call, I added that Petitioner still might be unable to advance a Table claim, due to the substantial deficiencies related to onset and a viable alternative cause. *Id.* at 8. I instructed the parties to exchange a demand and response to determine whether an informal settlement could be reached. *Id.*

[3] Although not notarized, the signed declaration was signed under penalty of perjury as required by 28 U.S.C.A. § 1746. Exhibit 5.

[4] This Fact Ruling can be found on the United States Court of Federal Claims website, and/or at https://www.govinfo.gov/app/collection/uscourts/national/cofc (last visited February 7, 2024) or using the following westlaw citation: *Kane v. Sec'y of Health & Hum. Sers.,* No. 21-0516V, 2023 WL 2885340 (Fed. Cl. Spec. Mstr. Apr. 11, 2023).

During the subsequent four-month prior, the parties exchanged multiple offers and counteroffers. *See* Joint Status Report, filed June 15, 2023, ECF No. 37. Petitioner also filed updated medical records, a supplemental declaration, and a declaration from her partner.[5] Exhibits 16-21, ECF Nos. 29, 31-33.

On July 17, 2023, Petitioner filed a status report, stating that "[s]ettlement discussions [had] failed [and] [f]ormal litigation will be necessary to resolve entitlement and damages." Status Report at 1, ECF No. 38. She added that she "intends to retain an orthopedic expert and proceed with briefing on entitlement and damages." *Id.* at 2. Instead, I directed the parties to file briefing and additional evidence regarding pain onset, stating that I would issue a factual finding. I instructed Petitioner to not retain an expert at this time.

On August 31, 2023, the parties filed their respective briefs. ECF Nos. 40-41. Discussing numerous cases in which pain onset within 48 hours was found despite Respondent's objections of a lack of specificity, vague language, and inconsistent descriptions, Petitioner insists she has provided preponderant evidence to support a finding of symptom onset within a medically appropriate temporal relationship. Memorandum of Law in Support of Petitioner's Motion for Findings of Fact Regarding Timing of Onset ("Pet. Brief") at 12-16, 18, ECF No. 40. Despite stressing that special masters have universally credited the medical records created closer in time to vaccination, she discounts her earlier statements that her pain was due to lifting luggage in preparation for and while on her trip. *Id.* at 16-17 (citing *Vergara v. Sec'y of Health & Hum. Servs.,* No. 08-0882V, 2014 WL 2795491, at *4 (Fed. Cl. Spec. Mstr. May 15, 2014). Instead, she relies upon her consistent association of her symptoms and the vaccine she received, made "[f]ollowing the appropriate workup by orthopedists." Pet. Brief at 18. Petitioner also emphasizes the opinion of her orthopedic surgeon who performed her arthroscopic surgery on November 18, 2020 - attributing her right shoulder injury to vaccination, insisting that it was based upon "a complete history." *Id.* at 17.

Respondent counters that "[P]etitioner has not established that the onset of her alleged shoulder injury occurred within the Table timeframe of forty-eight hours of vaccination. Respondent's Brief Addressing Onset at 1, ECF No. 41. Contrasting the circumstances in this case with those in *Kirby,*[6] Respondent insists that the medical records from Petitioner's initial visits clearly and consistently state that her symptoms

[5] Both declarations were signed under penalty of perjury as required by 28 U.S.C.A. § 1746. Exhibits 17-18.

[6] *Kirby v. Sec'y of Health & Hum. Servs.*, 997 F.3d 1378 (Fed. Cir. 2021) (finding the petitioner's assertion of six-months sequelae was not defeated by medical records that were silent on the matter – failing to address either the existence or nonexistence of any ongoing symptoms).

began two weeks post-vaccination, on October 15 or 16, 2020, and thus, should be afforded substantial weight. *Id.* at 18.

The next day, Petitioner filed an unsigned travel log and receipts (Exhibit 22) and impact statement signed by Petitioner,[7] describing her condition prior to and after her right shoulder pain (Exhibit 23). The travel log is not signed but describes daily activities during a trip taken by Petitioner and her partner in October 15 through 26, 2020, and includes copies of relevant receipts. The matter is now ripe for adjudication.

II. Issue

At issue is whether Petitioner's first symptom or manifestation of onset after vaccine administration (specifically pain) occurred within 48 hours as set forth in the Vaccine Injury Table and Qualifications and Aids to Interpretation ("QAI") for a Table SIRVA. 42 C.F.R. § 100.3(a) XIV.B. (influenza vaccination); 42 C.F.R. § 100.3(c)(10)(ii) (required onset for pain).

III. Authority

Pursuant to Vaccine Act Section 13(a)(1)(A), a petitioner must prove, by a preponderance of the evidence, the matters required in the petition by Vaccine Act Section 11(c)(1). A special master must consider, but is not bound by, any diagnosis, conclusion, judgment, test result, report, or summary concerning the nature, causation, and aggravation of petitioner's injury or illness that is contained in a medical record. Section 13(b)(1). "Medical records, in general, warrant consideration as trustworthy evidence. The records contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions. With proper treatment hanging in the balance, accuracy has an extra premium. These records are also generally contemporaneous to the medical events." *Cucuras v. Sec'y of Health & Hum. Servs*., 993 F.2d 1525, 1528 (Fed. Cir. 1993).

Accordingly, where medical records are clear, consistent, and complete, they should be afforded substantial weight. *Lowrie v. Sec'y of Health & Hum. Servs*., No. 03-1585V, 2005 WL 6117475, at *20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). However, this rule does not always apply. "Written records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent." *Murphy v. Sec'y of Health & Hum. Servs.*, No. 90-882V, 1991 WL 74931, *4 (Fed. Cl. Spec. Mstr. April 25,

[7] Although this statement was signed by Petitioner, the signature was not dated or provided under penalty of perjury as required by 28 U.S.C.A. § 1746. Exhibit 23.

1991), quoted with approval in decision denying review, 23 Cl. Ct. 726, 733 (1991), *aff'd per curiam*, 968 F.2d 1226 (Fed.Cir.1992)). And the Federal Circuit recently "reject[ed] as incorrect the presumption that medical records are accurate and complete as to all the patient's physical conditions." *Kirby v. Sec'y of Health & Hum. Servs.*, 997 F.3d 1378, 1383 (Fed. Cir. 2021).

The United States Court of Federal Claims has outlined four possible explanations for inconsistencies between contemporaneously created medical records and later testimony: (1) a person's failure to recount to the medical professional everything that happened during the relevant time period; (2) the medical professional's failure to document everything reported to her or him; (3) a person's faulty recollection of the events when presenting testimony; or (4) a person's purposeful recounting of symptoms that did not exist. *La Londe v. Sec'y of Health & Hum. Servs*., 110 Fed. Cl. 184, 203-04 (2013), *aff'd*, 746 F.3d 1335 (Fed. Cir. 2014).

The Court has also said that medical records may be outweighed by testimony that is given later in time that is "consistent, clear, cogent, and compelling." *Camery v. Sec'y of Health & Hum. Servs*., 42 Fed. Cl. 381, 391 (1998) (citing *Blutstein v. Sec'y of Health & Hum. Servs*., No. 90-2808, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998). The credibility of the individual offering such fact testimony must also be determined. *Andreu v. Sec'y of Health & Hum. Servs.*, 569 F.3d 1367, 1379 (Fed. Cir. 2009); *Bradley v. Sec'y of Health & Hum. Servs*., 991 F.2d 1570, 1575 (Fed. Cir. 1993).

A special master may find that the first symptom or manifestation of onset of an injury occurred "within the time period described in the Vaccine Injury Table even though the occurrence of such symptom or manifestation was not recorded or was incorrectly recorded as having occurred outside such period." Section 13(b)(2). "Such a finding may be made only upon demonstration by a preponderance of the evidence that the onset [of the injury] . . . did in fact occur within the time period described in the Vaccine Injury Table." *Id*.

The special master is obligated to fully consider and compare the medical records, testimony, and all other "relevant and reliable evidence contained in the record." *La Londe*, 110 Fed. Cl. at 204 (citing Section 12(d)(3); Vaccine Rule 8); *see also Burns v. Sec'y of Health & Hum. Servs*., 3 F.3d 415, 417 (Fed. Cir. 1993) (holding that it is within the special master's discretion to determine whether to afford greater weight to medical records or to other evidence, such as oral testimony surrounding the events in question that was given at a later date, provided that such determination is rational).

IV. Finding of Fact

I make this onset finding after a complete review of the record to include all medical records, statements, declarations, briefing, and additional evidence filed. Specifically, I base the findings on the following evidence:

- Prior to receiving the flu vaccine on October 2, 2020, Ms. Kane (then 68 years old) suffered from obesity; bipolar disorder; depression; vertigo; varicose veins; lumbar radiculopathy; generalized muscle aches and weaknesses and arthralgias and joint pain; pain in both feet and knees, the lower back, the right hip, and left shoulder; and other common conditions and illnesses. *E.g.,* Exhibit 6 at 5; Exhibit 9 at 31, 42. Although the entries related to prior hip and left shoulder pain did not include an onset date like many other entries, it appears these conditions occurred prior to late 2016. *See* Exhibit 9 at 91 (including the conditions on a December 2016 list of past diagnoses). Less than one year before vaccination, she received a cortisone injection in her left knee. *Id.* at 43.

- On October 2, 2020, Petitioner received the flu vaccine in her right deltoid. Exhibit 1 at 1.

- Nineteen days later, on October 21, 2020, while on vacation,[8] Petitioner visited an urgent care facility in Sacramento, California, complaining of severe right shoulder pain (rated as ten out of ten) and stiffness for the last five days.[9] Exhibit 2 at 2. She identified the date which corresponds to this time frame, October 16, 2020, as the date of onset. *Id.*

- Petitioner answered in the negative when asked about specific injuries or occurrences that coincided with her symptom onset, such as an injury or motor vehicle accident. Exhibit 2 at 2. However, there is a handwritten entry above these questions stating: "super flu shot" on right deltoid one week ago. *Id*. The responses and handwritten entry appear to have been provided by the individual who took Petitioner's vital signs. In the portion completed by the urgent care physician, it is noted that Petitioner thought her pain was

[8] Receipts provided by Petitioner show that she and her partner traveled by plane from Tampa, Florida to Milwaukee, Wisconsin on October 15, 2020, with a return trip on October 26, 2020. Exhibit 23 at 20-23. From October 17 through 24, 2020, Petitioner and her partner traveled by train from Milwaukee, Wisconsin to Portland, Oregon; Sacramento, California; Chicago, Illinois; and back to Milwaukee, Wisconsin. *Id.* at 24-28.

[9] Although I will cite to Exhibit 2, the medical record from this visit is also filed as Exhibit 8. *Compare* Exhibit 2 *with* Exhibit 8.

"from lifting luggage. Has been traveling by plane & train." *Id.* The urgent care provider diagnosed Petitioner as having muscle strain, prescribed pain medication, and instructed her to stretch, to apply ice, and to take Ibuprofen. *Id.* at 3, 5.

- Eight days later, on October 29, 2020, Petitioner was seen by her orthopedist for right shoulder pain currently at a level of three out of ten, but which could increase with movement or at night to nine out of ten. Exhibit 3 at 13-14. She also described "numbness; tingling; catching/locking; [and] popping/clicking." *Id.* at 13. Reporting no known injury, Petitioner listed October 15, 2020, as the onset date. *Id.* Petitioner stated that she "was on vacation and traveling by train when pain started." *Id.* at 13-14 (the entry is discernable despite the words location on both pages). Petitioner added that she had visited an urgent care clinic in California. *Id.* at 14.

- Upon examination, Petitioner was noted to have limited range of motion ("ROM"), and ex-rays showed a large calcium deposit in her rotator cuff. Exhibit 3 at 14-15. The orthopedist diagnosed Petitioner with calcific tendinitis of the right shoulder, ordered an MRI, and indicated a steroid injection and/or surgery should be considered thereafter. *Id.* at 15.

- On November 5, 2020, Petitioner underwent an MRI. Exhibit 3 at 10 (record from November 18th orthopedic visit). Although Petitioner's orthopedist discussed the MRI results at Petitioner's next orthopedic visit, it does not appear that the report from this MRI was filed.

- When Petitioner returned to the orthopedist on November 10, 2020, she reported that her right shoulder pain had improved slightly since the last visit but was worse than at onset. Exhibit 3 at 8. The record from this visit again lists October 15, 2020, as the onset date. *Id.*

- After reviewing the results of her MRI – showing "a large calcium deposit of RC involving the entire rotator cuff, severe subacromial swelling, [and] no evidence of full thickness tear" (Exhibit 3 at 10), the orthopedist recommended surgery to remove the calcium deposit (*id.* at 9). He ordered a sling and physical therapy ("PT") to begin ten to 14 days post-surgery. *Id.* at 10. This record, however, includes a complete rotator cuff tear or rupture, along with calcific tendinitis and pain, in the list of diagnoses. *Id.*

- On November 18, 2020, Petitioner underwent arthroscopic surgery involving rotator cuff repair, subacromial decompression, distal clavicle

resection, and extensive debridement including excision of the large calcium deposit. Exhibit 9 at 99. The "Indications for Operation" portion of the surgical report, contains the following history:

> This is a 68-year-old female who received a flu vaccine in early October of 2020. She had severe postinjection pain and visited the ER within days of being vaccinated. She was given narcotic pain medication and then referred to my office. An MRI scan and x-rays confirmed a large calcium deposit in the rotator cuff tear with partial thickness tearing of the rotator cuff.

Id. at 100 (section title is in all capitalized letters in the original). In the same section, the orthopedic surgeon noted that Petitioner "also had all the classic signs and symptoms of vaccine induced hyper inflammatory reaction in the subacromial space [which [s]he was able to manage nonsurgically." He added that he had discussed the risks and benefits of surgery with Petitioner. *Id.*

- In the post-surgical report, the surgeon reported the following:

> This procedure required excision of a large calcium deposit in the rotator cuff, which resulted in a defect after excision, the calcium deposit within the rotator cuff was likely causing at least some degree [of] chemical irritation . . . [but] there was profound inflammatory reaction within the subacromial space and subacromial bursa likely related to vaccination, hyper inflammation.

Exhibit 9 at 101.

- At her first post-surgical visit with her orthopedist on November 23, 2020, Petitioner was cleared to begin PT. Exhibit 3 at 5. She attended 19 PT sessions from November 30th through February 22, 2021. Exhibits 4, 12.

- Petitioner first attended PT on November 30, 2020. Exhibit 4 at 2-4. At her next session on December 3, 2020, she reported a little improvement after performing her home exercise program. *Id.* at 5. She further reported that "she had a flu shot back in October on her right shoulder and it was hurting

a lot, it continued with pain all this time and was told the flu shot cause[d] some inflammation around the bursae." *Id.*

- Also on December 3, 2020, Petitioner visited her primary care provider ("PCP") for an annual exam. Exhibit 6 at 7-9. She reported having COVID back in February 2020, developing "right shoulder bursitis following flu vaccine," and undergoing right rotator cuff surgery to repair a tear. *Id.* at 8. Beside the bursitis diagnosis, it is noted that Petitioner had filed a lawsuit. *Id.* at 9.

- The first copy of the medical records from Petitioner's urgent care visit in Sacramento, California, appears to have been provided in early December 2020. *See* Exhibit 2 at 1 (signature of individual certifying the records authenticity dated December 9, 2020). The second copy appears to have been provided on January 26, 2021. *See* Exhibit 8 at 1. Most medical records were requested in January 2021. *E.g.,* Exhibit 6 at 1; Exhibit 7 at 2.

- By her second post-surgical orthopedic visit on December 21, 2020, Petitioner reported that she was attending PT twice a week, had no pain currently, and could experience pain as severe as eight of out ten at night. Exhibit 9 at 9. Observing that Petitioner's incisions were healing well, the orthopedist instructed her to transition to over-the-counter pain medication, to continue using her sling and attending PT, and to perform any tolerable activity. *Id.* at 10.

- In her first declaration, Petitioner addressed three basic requirements for compensation: 1) receipt of a covered vaccine; 2) vaccine administered within the United States; and 3) a lack of a pending civil action or compensation. Exhibit 5. Petitioner did not address the onset of her symptoms, including right shoulder pain. *See id.*

- In her second declaration, Petitioner focused on the difficulties caused by her alleged SIRVA. Exhibit 17. Her partner's declaration, filed at the same time. also primarily discussed the effects of Petitioner's alleged injury. Exhibit 18. Again, both declarations failed to address the onset of Petitioner's symptoms. *See* Exhibits 17-18.

- The travel log and receipts provided in September 2023, showed Petitioner and her partner traveled by plane on October 15 and 26, 2020, and by train October 17 through 24, 2020. Exhibit 22. Although the travel log provides detailed descriptions of each day's activities, it is not signed or dated. *Id.*

Additionally, both Petitioner and her partner are referred to in the third person, making it difficult to determine who created these journal entries. *Id.* The first paragraph states that they stopped at a store on the way to the airport on October 15, 2020, to buy pain relief patches because "Cathy's neck and upper shoulder bothered her last night and was still sore this morning." *Id.* at 2.

- In her impact statement, also provided in September 2023, Petitioner stated that she "felt a little icky" after returning home after her flu shot. Exhibit 23 at 3. She "took Ibuprofen an put ice on [her] shoulder . . . [and] [s]tarted sleeping in [her] recliner." *Id.* Describing her right shoulder pain as "not constant, but com[ing] on suddenly and intense," Petitioner stated that she "thought [she] may have pulled a muscle in [her] shoulder packing and prepping for the trip." *Id.* at 4. She also gathered the hydrocodone pills given to her earlier by her dentist and bought supplies at a CVS store on the drive to the airport in Tampa, Florida. *Id.* In the remainder of the impact statement, Petitioner discusses the difficulties she endured during her trip and after she returned home. *See* Exhibit 23.

When Petitioner first sought treatment for her right shoulder pain, in October and early November 2020, she consistently identified an onset date in mid-October 2020, approximately two weeks post-vaccination. Exhibit 2 at 2; Exhibit 3 at 13, 8 (in chronologic order). Indeed, she pinpointed exact dates of either October 15th or 16th. *Id.* And Petitioner provided detailed information about the events occurring at the time of her pain onset that coincides with the evidence in this case. Exhibit 2 at 2; Exhibit 3 at 13. For example, when first seen by her orthopedist on October 29, 2020, Petitioner clearly stated that she "was on vacation and traveling by train when [her] pain started." Exhibit 3 at 13-14. Travel receipts show she began her trip on October 15, 2020. *See supra* note 8.

Furthermore, Petitioner attributed her right shoulder pain to her physical activities at that time. When first seen at an urgent care facility on October 21, 2020, Petitioner theorized that her pain may be due to lifting luggage, noting she had been traveling by plane and train. Exhibit 2 at 2. Although Petitioner mentioned her flu shot at this visit, she did not propose a causal connection. Even if she had, it would not counter the mid-October pain onset she reported since she mistakenly stated the vaccination occurred on October 13, 2020. *See id.*

The Federal Circuit's holding in *Cucuras* dictates that I afford these initial representations greater weight. All were provided within two weeks of the identified onset date for the purpose of obtaining medical care. *See Cucuras,* 993 F.2d at 1528 (listing the importance of these factors). And the information contained in these records are clear,

consistent, and complete. *See Lowrie*, 2005 WL 6117475, at *20. Also, the provided receipts show travel dates which are consistent with these statements. Exhibit 23 at 20-28.

Even when asserting an earlier pain onset date in subsequent statements provided during litigation, Petitioner continued to focus on pain that began in mid-October, connecting it to her physical activity when packing for and traveling on her trip (October 15-27, 2020). For example, in the travel journal entry, provided almost three years post-vaccination, the author recalled on October 15th that Petitioner's "neck and upper shoulder bothered her last night and were still sore this morning," placing the onset of this episode of pain and soreness during the evening of October 14, 2020. Exhibit 22 at 1.

Petitioner did not report a pain onset within 48 hours of vaccination, or attribute her symptoms to the flu vaccine she received on October 2, 2020, until seen by her orthopedic surgeon on *November* 18, 2020, the date of her arthroscopic surgery. Exhibit 9 at 100. And her report included a reference to an emergency room visit "within days of being vaccinated," for which there is no proof. *Id.* Furthermore, this first report of immediate post-injection pain was provided by Petitioner only two weeks before visits to her PCP and physical therapist – at which times she also mentioned that she was filing a lawsuit and seeking compensation for her injury. Exhibit 4 at 5; Exhibit 6 at 9. This fact does not negate the provided information, but it does somewhat diminish the weight it should be afforded.

Petitioner suggests these later representations should be afforded greater weight because they were made after "the appropriate workup by orthopedists." Pet. Brief at 18. However, the record contains no evidence showing Petitioner's orthopedist connected her right shoulder symptoms to a vaccine injection. *See* Exhibit 3. Instead, he attributed Petitioner's symptoms to the large calcium deposit and rotator cuff tear seen on x-rays and an MRI. *Id.* at 15. And he proposed surgery to remove this calcium deposit. *Id.* at 9.

The first treating physician to connect Petitioner's symptoms to the flu vaccine she received was the orthopedic surgeon who first saw Petitioner on October 18, 2020, when he performed her arthroscopic surgery. And he did so based upon the history provided by Petitioner of immediate pain upon vaccination and a trip to the emergency room a few days later (which would be October 4, 2020). Exhibit 9 at 100. Despite Petitioner's arguments to the contrary, I find the orthopedic surgeon's causal opinion was not based upon a complete or accurate history. *See* Pet. Brief at 18.

Other than these histories provided by Petitioner in the medical records from later visits to her surgeon, PCP, and physical therapist, the only evidence suggesting right

shoulder pain that began with vaccination and continued thereafter can be found in the impact statement signed by Petitioner. However, the statement lacks any signature date or language stating it was signed under penalty of perjury. Exhibit 23 at 3-4 (onset description), 12 (signature page). And it also contains information pointing to at least an increase in pain while packing for her October 15th trip, and the suggestion that Petitioner may have pulled a muscle at that time. Furthermore, the unsigned travel log completed by Petitioner or her partner, supports this account of pain when packing for her trip. One entry describes a stop for icy patches on the drive to the airport on October 15th, because Petitioner's "neck and upper shoulder bothered her last night and was still sore this morning." Exhibit 22 at 1.

Here, the medical records created closer in time to the onset of Petitioner's right shoulder pain contain clear and convincing evidence supporting a pain onset in mid-October 2020. Thus, the circumstances in this case differ from those in *Kirby* which involved medical records that were silent on the issue in dispute (meaning the records merely omitted mention of a disputed issue). *Kirby,* 997 F.3d 1378, at 1383. While later provided medical histories offer *some* evidence of an earlier pain onset, they are not sufficient to counter the strong evidence that predates these later records created less than two months prior to the petition's filing. Accordingly, I find the preponderant evidence supports a finding that Petitioner's right shoulder pain began in mid-October 2020, approximately two weeks post-vaccination and later than the pain onset within 48 hours of vaccination required for a Table SIRVA claim.

V. Potential for Off-Table Claim

A petitioner's failure to establish a Table injury does not necessarily constitute the end of a case under all circumstances, because he or she might well be able to establish a non-Table claim for either causation-in-fact or significant aggravation. *See Althen v. Sec'y of Health & Hum. Servs.*, 418 F.3d 1274 (Fed. Cir. 2005); *W.C. v. Sec'y of Health & Hum. Servs.*, 704 F.3d 1352, 1357 (Fed. Cir. 2013) (citing *Loving v. Sec'y of Health & Hum. Servs.*, 86 Fed. Cl. 135, 144 (2009)).

Although unlikely given the amount of time between vaccination and onset, and with ample evidence supporting other causes for Petitioner's symptoms, it is still possible that Petitioner may be able to prove that the flu vaccine caused her right shoulder injury. However, she will need to provide additional evidence of a causal link and appropriate time frame between the flu vaccine she received and her right shoulder pain.

Formal resolution of this issue will likely require further review and most likely the retention of experts, which I am not inclined to authorize in the SPU. However, I will first

allow the parties an additional 30 days to determine if an informal resolution can be reached. Thereafter, I will transfer the case out of SPU.

Conclusion

Petitioner has not established the onset of her right shoulder pain occurred within 48 hours of her receipt of the flu vaccine on October 2, 2019. **Accordingly, her Table SIRVA claim is dismissed.**

Because Petitioner *may* prevail on an off-Table claim, the parties should make one more attempt to reach an informal settlement in this case, before I reassign it out of SPU. **The parties shall file a joint status report indicating whether they believe an informal settlement could be reached in this case and updating me on their current efforts by no later than Friday, May 31, 2024**.

IT IS SO ORDERED.

s/Brian H. Corcoran
Brian H. Corcoran
Chief Special Master